Claims. **PCT amended Sep 2004**

1. A closure system for a vial of the type having an upwardly-facing mouth opening bounded by a rim, the closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial,

a cover part, engageable with the clamp part and/or the vial to cover the said region of the closure part, the cover part at least partly closing the aperture,

characterised by the cover part comprising an upper wall which has a segment linked to the remainder of the cover part by one or more thin frangible link which can easily be severed to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture.

2. A closure system according to claim 1 *characterised* in that a lower surface of the segment of the cover part facing the upper surface of the closure part when engaged with the clamp part has a sealing ridge projecting therefrom to a sealing edge that follows a closed perimeter, so that when the cover part is engaged with the clamp part and/or the vial the sealing edge engages with the closure part to form an enclosure with the closure part, the segment which includes the sealing ridge being detachable from the clamp part and/or the vial.

3. A closure system according to claim 1 or 2 *characterised* in that the cover part comprises a cap comprising the upper wall and a peripheral skirt wall, and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part.

4. A closure system according to claim 3 *characterised* in that the upper wall of the cover part has the segment linked to the remainder of the upper wall and/or skirt wall of the cover part by the one or more thin frangible link.

5. A closure system according to any one of the preceding claims *characterised* by a downwardly extending plug part which can fit into the mouth opening of the vial, and an outwardly extending peripheral flange part, a downward facing surface of which can engage with the upward facing surface of a rim of the vial mouth opening in the form of a flange, and wherein upwardly of the flange part the closure part is upwardly convex.

6. A closure system according to claim 5 *characterised* in that the clamp part comprises an upper wall part having the aperture therein, with peripheral skirt walls extending downwardly therefrom and having snap-fit engagement parts thereon to engage with the vial, and the upper wall and the upwardly convex part of the closure part are profiled such that the upwardly convex part bulges above the adjacent upper surface of the upper wall.

7. A closure system according to claim 5 or 6 *characterised* in that the upper surface of the clamp part and the upwardly convex part of the closure part are profiled to form a smooth convex shape.

8. A closure system according to any one of the preceding claims *characterised* in that at least the upper surface of the closure part adjacent to the said region is made of a thermoplastic elastomer material, so that a puncture hole formed as a result of filling the vial using a hollow needle may be sealed by thermal sealing.

9. A closure system according to any one of the preceding claims *characterised* in that the clamp part is made of a mouldable plastics material, and is engageable with the rim bounding the mouth opening of the vial.

10. A pharmaceutical vial *characterised* by a mouth opening closed by a closure system according to any one of the preceding claims.

11. A method of closing a vial, wherein:

a vial is provided being of the type having an upwardly-facing mouth opening bounded by a rim in the form of a flange having upper and lower surfaces extending transverse to its upper-lower axis.

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface to face the interior of the vial and an opposite upper surface to face away from the vial, and capable of being punctured by a needle is inserted into the mouth opening of the vial,

a clamp part is provided able to engage with the flange around the rim of the mouth opening of the vial by a resilient snap-fit engagement of a snap fit part of the clamp part underneath a downwardly facing surface of such a flange part, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, and

the clamp part is engaged with the assembly of vial and closure part by said snap-fit engagement,

then subsequent to the engagement of the clamp part with the assembly of vial and closure a cover part is provided, engageable with the clamp part and/or the vial to cover the closure part when so engaged, a lower surface of the cover part to face the upper surface of the closure part when so engaged, and

the cover part is engaged with the clamp part by means of a snap-fit between the cover part and the clamp part.

12. A method of filling a pharmaceutical vial, comprising the steps of:

providing an assembly of an empty vial having an elastomer closure part shaped to sealingly engage with the mouth opening and having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle, and a clamp part engaged with the vial, and bearing upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture

therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial;

inserting a filling needle downwardly through the region of the upper wall of the closure part;

injecting a liquid medicament through the filling needle to fill the vial to a suitable extent;

withdrawing the needle to leave a residual puncture hole;

engaging a cover part with the clamp part and/or the vial to cover the said region of the closure part by means of a snap-fit between the cover part and the clamp part.

13. A method according to claim 12 *characterised* in that prior to engaging the said cover part a source of heat is directed at that part of the upper surface of the closure part where the puncture has occurred to melt the elastomer material in the immediate locality of the puncture, and to thereby seal the residual puncture hole.

14. A vial closure having a plug part which has an outward-facing neck-contacting surface which is cylindrical adjacent the lower end of the plug part, and which engages with the interior surface of the vial neck when the closure is in place is against the cylindrical interior surface of the vial neck, and an interior-facing surface which is exposed to the interior of the vial and which when the closure is in place on a vial encloses an angle of 120 - 160° with the interior surface of the vial neck immediately below the plug part.

15. A vial closure according to claim 15 *characterised* in that the angle is 135° +/- 10°.

16. A vial of the type having an upwardly-facing mouth opening bounded by a rim, *characterised* in that its mouth is closed by closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle;

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial,

and optionally a cover part, engageable with the clamp part and/or the vial to cover the said region of the closure part;

in combination with a stand for the vial comprising a ring-shaped body having an inner perimeter adapted to engage with the base of the vial, the stand having an outer perimeter which extends radially beyond the outer diameter of the vial body in a direction perpendicular to the mouth-base axis direction of the vial retained therein, to substantially the same radial distance as the radially outermost extent of the combination of the vial and clamp part and/or cover part.